

Producer: VUP Medical, a.s.

Address: Šujanovo náměstí 302/3, 602 00 Brno, Czech Republic

ID No.: 15546578

Issue:

ES DECLARATION OF CONFORMITY

Pursuant to § 13 (2) of the Act No. 22/1997 Coll., on technical requirements for products and amendment of some Acts, in conjunction with the Act No. 268/2014 Coll., on the medical devices, and pursuant to the Czech Government Order No. 54/2015 Coll., on technical requirements for medical devices, and pursuant to the Council Directive 93/42/EEC on medical devices.

Name of the medical device:

Knitted vascular prosthesis with collagen Ra K

Use: For arterial reconstructions. These types of prostheses can be used in aorto-femoral, ilio-femoral, femoropopliteal zones above the knee joint, in the zones of extra-cranial arteries and for extra-anatomical bypasses.

Class: III

Notification Body: Polish Centre for Testing and Certification, PCBC (NB No. 1434)

Address of Notification Body: ul. Puławska 469, 02-844 Warsaw, Poland

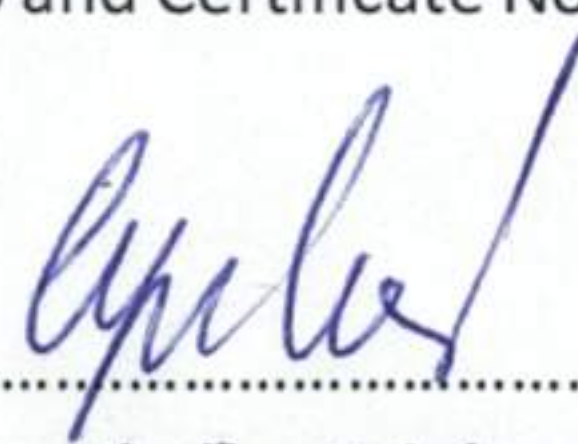
The producer hereby declares that the properties of the above-mentioned medical device meet all the essential requirements set out in the Czech Government Order No. 54/2015 Coll., and that in normal use for its purpose the medical device is safe, effective and suitable for use in health care. The producer furthermore declares that he has taken measures with which he secures the conformity of all packages of the above-mentioned medical device, with the essential requirements and with its technical documentation.

The following were used for the conformity assessment:

- Annex II of the Directive 93/42/EEC, as amended.
- Quality management system according to ČSN EN ISO 9001:2016 – Certificate No. 18 0092 SJ, issued by ITC, a.s.; Certificate No. CQS 2237/2018, issued by CQS Prague; Certificate No. CZ – 2237/2018, issued by IQNet.
- Quality management system according to ČSN EN ISO 13485 ed. 2:2016 – Certificate No. 18 0093 SJ, issued by ITC, a.s.; Certificate No. CQS 216/2018, issued by CQS Praha; Certificate No. CZ – 216/2018, issued by IQNet.

The products are covered by Certificate No. 1434-MDD-340/2020 and Certificate No. 1434-MDD-341/2020 issued by NB No. 1434 PCBC, Warsaw.

In Brno 3. 11. 2020



Vladka Cejpková
Board member of VUP Medical, a.s.